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Original Article

Feasibility of a decentralised trial of sleep apnoea screening in patients with atrial fibrillation

Mads Hashiba[1], Ali Al-Alak[1], Sebastian Kinnberg Nielsen[1], Lars Kayser[2], Nina Nouhravesh[1], Mariam Elmegaard[1], Mohamed El-Chouli[1, 3], Signe Risom[1, 4, 5], Rune Asger Vestergaard Frandsen[6], Poul Jennum[6] & Morten Lamberts[1, 5]

1) Department of Cardiology, Copenhagen University Hospital – Herlev and Gentofte Hospital, 2) Department of Public Health, University of Copenhagen, 3) Department of Cardiology, Zealand University Hospital, Roskilde, 4) Institute for Nursing and Nutrition, University College Copenhagen, 5) Department of Clinical Medicine, University of Copenhagen, 6) Danish Center for Sleep Medicine, Department of Neurophysiology, Copenhagen University Hospital – Rigshospitalet, Denmark

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ABSTRACT

INTRODUCTION. Atrial fibrillation (AF) prevalence is projected to double in the coming decades, necessitating innovative management strategies. This study evaluated the feasibility of a decentralised clinical trial for home-based sleep apnoea (SA) screening, activity tracking and heart rhythm monitoring in patients with AF.

METHODS. This prospective cohort study enrolled patients with AF without known SA. Participants underwent a 12-week study using three home-monitoring systems: NightOwl for SA evaluation, FibriCheck for heart rhythm monitoring and SENS Motion for activity tracking. Patients completed questionnaires assessing AF-related quality of life, symptom severity, sleep quality and eHealth literacy at baseline and 12 weeks.

RESULTS. The study included 18 patients with AF with a median age of 68.0 (interquartile range: 60.0-71.5) years, 11 (61%) women and 15 (83%) with paroxysmal AF. The study demonstrated high feasibility of remote monitoring, with data completeness rates of 83.3% for SA home evaluations, 97.6% for questionnaires, 91.7% for activity tracking and 88.8% for heart rhythm measurements. A drop-out rate of only 5.6% was recorded.

CONCLUSIONS. The study reports the feasibility of a decentralised digital platform for comprehensive AF patient monitoring. High patient engagement and data completeness suggest that digital health technologies can effectively integrate into clinical trials for patients with AF.

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As the prevalence of atrial fibrillation (AF) is projected to double in the coming decades, innovative management strategies are essential [1]. Decentralised clinical trials (DCTs) offer a patient-centred approach that uses technology to improve accessibility, data collection and inclusivity [2]. Real-time monitoring through wearables enables patients with AF to track symptoms and manage underdiagnosed risk factors like sleep apnoea (SA), a condition which is prevalent in this population [3, 4]. By supporting remote data collection and personalised care, DCTs empower patients, reduce the need for study personnel and ease burdens on traditional research sites. This approach also allows for better capture of unpredictable symptoms of AF, improving data accuracy.

Studies highlight the high prevalence of SA in patients with AF. Our group's findings revealed that 56% (71/126) of patients with AF had moderate to severe SA and were eligible for treatment [4]. Despite this, SA remains underrecognised, with optimal screening tools being absent from the 2024 European Society of Cardiology (ESC) Guidelines [5]. Given that standard SA screening questionnaires are poor predictors of moderate to severe SA in patients with AF, a new approach to SA evaluation is urgently needed [6].

Emerging technologies, such as miniaturised monitors and advanced algorithms, provide an opportunity for innovative risk factor management. Remote enrollment and monitoring can support evaluation of new screening tools and their impact on care, outcomes and prognosis [7].

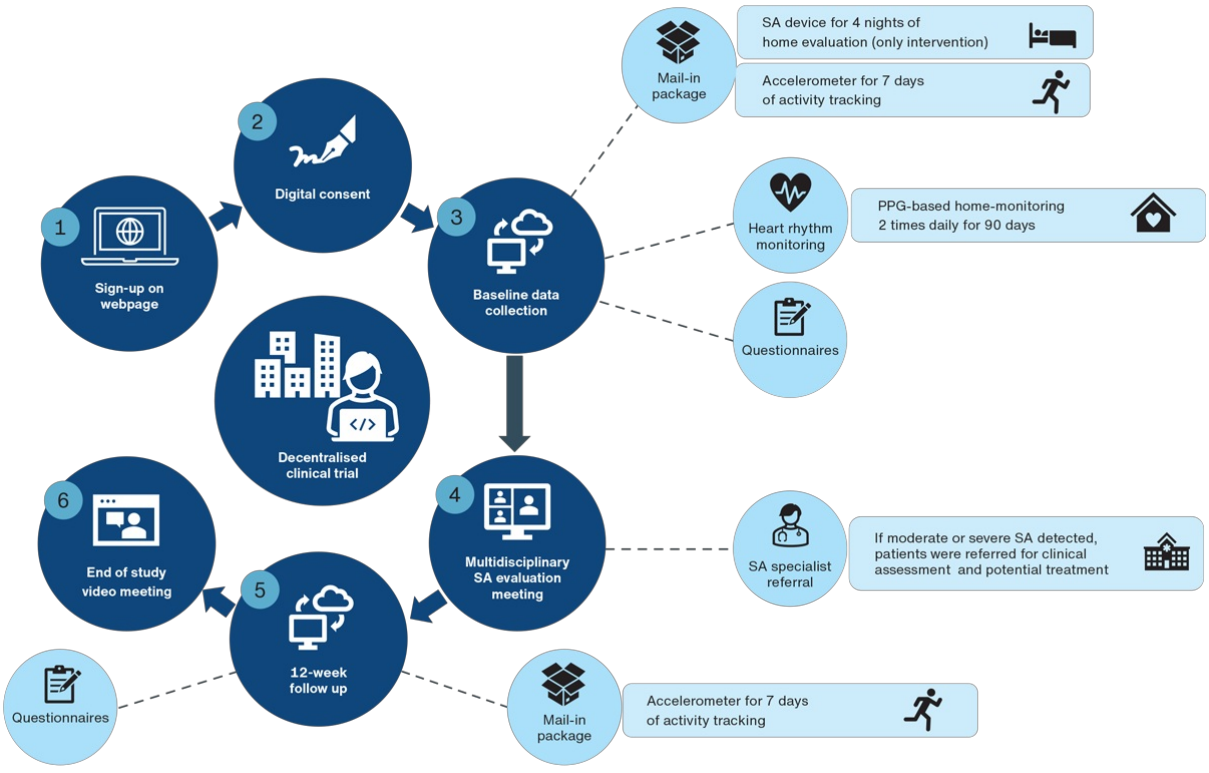
We aimed to evaluate the utility and feasibility of SA home evaluation in patients with AF. This included assessing the feasibility of estimating the effects of SA screening and treatment on health outcomes through questionnaires, physical tracking and heart rhythm monitoring.

Methods

Participants and study design

This prospective cohort study enrolled patients with established paroxysmal or persistent AF who had not previously undergone investigation for sleep-disordered breathing. Patients were recruited through online registration from April 2023 to April 2024, with follow-up at 12 weeks. The eligibility criteria included owning a compatible smartphone and the absence of both heart failure (New York Heart Association class III/IV) and peripheral arterial disease with daily intermittent claudication. Patients were recruited online; completed baseline assessment and home monitoring for SA, activity tracking and heart rhythm; and participated in follow-up over 12 weeks (**Figure 1**).

FIGURE 1 Study design.



PPG = photoplethysmography; SA = sleep apnoea.

Sign-up and inclusion

Patients registered via the VIR SAAF Study website. After phone contact and an introductory online meeting with the investigator, digital informed consent was obtained. Eligibility was confirmed through electronic health records, ensuring that the inclusion and exclusion criteria were met.

Baseline data collection

On the day of inclusion, participants received a mail-in package containing the NightOw device for SA evaluation (four nights), a SENS Motion sensor for activity tracking (seven days) and instructions for twice-daily heart rhythm monitoring using the FibriCheck app (90 days). An online survey was also sent, including the Atrial Fibrillation Effect on QualiTy-of-life (AFEQT) [8], the Atrial Fibrillation Severity Scale (AFSS) [9], the Pittsburgh Sleep Quality Index (PSQI) [10] and the eHealth Literacy Questionnaire (eHLQ) [11].

Sleep apnoea evaluation and follow-up

After SA monitoring, patients with moderate to severe SA were referred to sleep physicians for clinical assessment and potential treatment. At 12 weeks, follow-up activity tracking and questionnaires were completed. The study results were shared with participants during a final video meeting.

The devices

The NightOwl system uses photoplethysmography (PPG) to capture data on actigraphy, oxygen saturation, peripheral artery tone and heart rate. Patients wore the device for four nights, and it provided diagnostic variables following American Academy of Sleep Medicine (AASM) guidelines for SA evaluation [12].

The FibriCheck system uses the camera and flashlight of a smartphone to record PPG signals from the fingertip, enabling heart rhythm and rate analysis. Validated against a 12-lead electrocardiogram with 96% sensitivity and 97% specificity for detecting AF [13], it recorded one-minute measurements twice daily for 90 days.

The SENS Motion system includes a thigh-worn accelerometer that tracks physical activity using a validated algorithm. It classifies inactivity, standing and movement with accuracies of 99%, 95% and 97%, respectively [14]. Patients wore the sensor for seven days at baseline and again at 12 weeks; data were transmitted wirelessly to a smartphone app and securely uploaded to a web platform for analysis.

Questionnaires

The eHLQ is a validated, multidimensional instrument with 35 items across seven scales, based on the eHealth Literacy Framework [15]. It assesses knowledge, skills and experiences in using digital health services and technology. Each scale comprises 4-6 items with a four-point response option. This study utilised the scales eHLQ1 ("Using technology to process health information"), eHLQ2 ("Understanding health concepts and language"), eHLQ3 ("Ability to engage with digital services"), eHLQ5 ("Motivation to engage with digital services") and eHLQ7 ("Digital services that suit individual needs"). Higher scores reflect better eHealth literacy [11].

The AFEQT assesses AF burden, with scores ranging from 0 (worst) to 100 (best) [8].

The AFSS questionnaire measures symptom severity, with scores ranging from 0 (best) to 35 (worst) [9].

PSQI evaluates sleep quality, with scores ranging from 0 (best) to 21 (worst) [10].

Outcomes

To evaluate the feasibility of SA home evaluation, physical tracking, heart rhythm monitoring and questionnaires in a completely virtual setting, the following outcomes were included:

Dropouts were defined as patients who did not complete the 12-week study period after providing informed

consent and receiving the package with the devices.

SA Home Evaluations Completeness was measured by the number of SA home evaluation nights not performed versus the total expected nights.

Physical Activity Tracking Completeness was assessed by the number of days of activity tracking not monitored versus the total expected days.

Heart Rhythm Monitoring Completeness was defined as heart rhythm measurements not obtained versus the total expected measurements.

Questionnaire completeness was defined as the number of completed questionnaires versus the total expected questionnaires.

Statistical analysis

Demographic data were reported as medians with IQR or means with standard deviation for continuous variables, and as absolute numbers and percentages for categorical variables. Dropout was assessed by tracking eligible patients who did not consent, those not completing the first survey and those who opted out. Missing data were evaluated by counting incomplete heart rhythm measurements, missed SA home evaluations and uncompleted seven-day SENS Motion tracking.

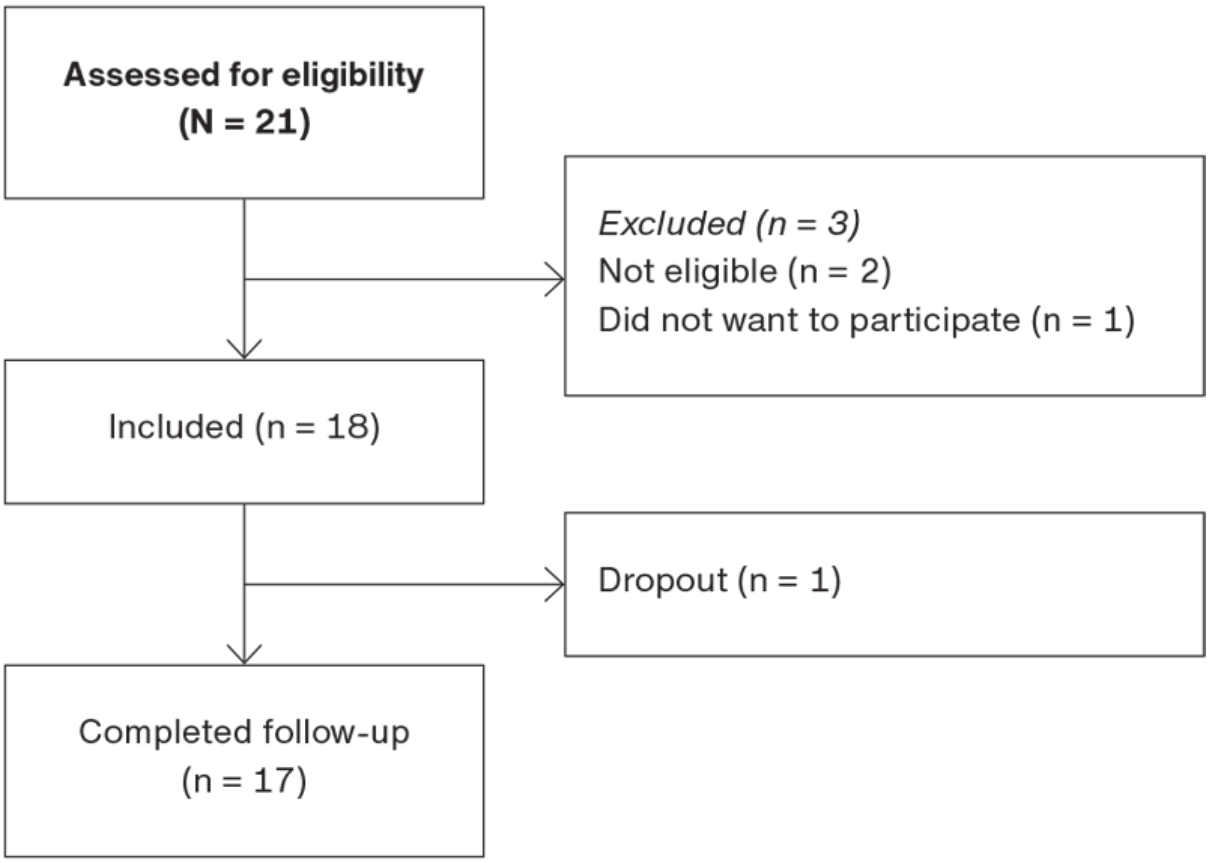
Trial registration: NCT06188247.

Results

Participant characteristics

A total of 21 patients were screened for the study, and 18 patients were enrolled in this feasibility study. Among the 18 patients, 17 completed the 12-week follow-up. One patient dropped out after changing his mind about participation (**Figure 2**).

FIGURE 2 Selection of population.



Basic demographic data and the patients' health literacy were collected at inclusion (**Table 1**). The median age was 68 years (60-71) and 61% [11] were females. Among the 18 patients, 83% [15] had paroxysmal AF, whereas 17% [3] had persistent AF. The average score of the five eHLQ domains was: eHLQ1 (3.2 ± 0.6), eHLQ2 (3.2 ± 0.4), eHLQ3 (3.3 ± 0.4), eHLQ5 (2.9 ± 0.4) and eHLQ7 (2.9 ± 0.6).

TABLE 1 Demographics, clinical characteristics, medication and eHealth Literacy Questionnaire information about the study population (N = 18).

Age, median (IQR), yrs	68.0 (60.0-71.5)
Women, n (%)	11 (61.1)
BMI, median (IQR), kg/m²	25.3 (23.1-30.3)
Blood pressure, median (IQR), mmHg	
Systolic	129.0 (123.0-135.0)
Diastolic	80.0 (72.0-84.0)
Atrial fibrillation type, n (%)	
Paroxysmal	15 (83.3)
Persistent	3 (16.7)
Ablation	
Previous ablation, n (%)	6 (33.3)
Ablations, mean (± SD), n	1.5 (± 0.6)
Cardioversion	
Previous cardioversion, n (%)	3 (16.7)
Cardioversions, mean (± SD), n	4.3 (± 4.2)
EHRA score, n (%)	
I	5 (27.8)
IIa	3 (16.7)
IIb	7 (38.9)
III	3 (16.7)
IV	0
CHA_2DS_2-VASc, mean (± SD)	
Women	2.4 (± 0.8)
Men	1.7 (± 1.0)
Comorbidity, n (%)	
COPD	0
Asthma	3 (16.7)
Ischaemic heart disease	0
Hypertension	8 (47.1)
Stroke/TIA	2 (11.1)
Peripheral artery disease	0
Heart failure	1 (5.6)
Heart valve disease	1 (5.6)
Thromboembolic events[a]	0
Diabetes type 2	2 (11.1)
Hypercholesterolaemia	9 (52.9)
Renal disease	0
Thyroid disease	0
Medication, n (%)	
Statins	8 (44.4)
Ezetimibe	2 (11.1)
Anticoagulation:	
Apixaban	8 (44.4)
Rivaroxaban	4 (22.2)
Edoxaban	2 (11.1)
RAS inhibitors	4 (23.5)
Beta-blockers	8 (47.1)
MRA	2 (11.8)
Diuretics	1 (5.6)
CCB	2 (11.8)
Flecainid	1 (5.6)
Metformin	1 (5.6)
eHLQ, mean (± SD)	
1	3.2 (± 0.6)
2	3.2 (± 0.4)
3	3.3 (± 0.4)
5	2.9 (± 0.4)
6	2.9 (± 0.6)

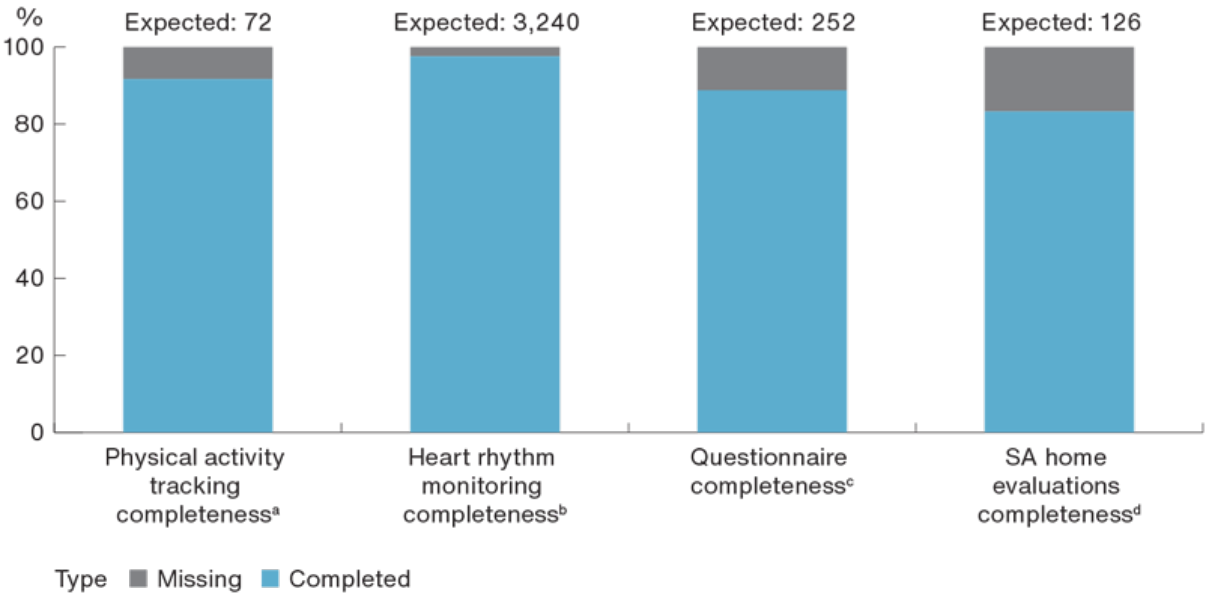
CCB = calcium channel blocker; eHLQ = eHealth Literacy Questionnaire; EHRA = European Heart Rhythm Association; MRA = mineralocorticoid receptor antagonist; RAS = renin-angiotensin system; SD = standard deviation; TIA = transient ischaemic attack.
a) Defined as either an event of deep vein thrombosis or pulmonary embolism.

Completeness of data

The complete overview of data completeness, including the proportions of completed and missing data across the different home-monitoring measures, is illustrated in **Figure 3**. Among the 72 expected nights of SA home evaluation (four nights per patient), 60 (83.3%) nights were completed. No patient missed all nights, with a maximum of two missing nights per patient. For the questionnaires, 123 (97.6%) out of 126 (four baseline questionnaires and three follow-up questionnaires per patient) were completed. Among the 252 expected days of activity tracking (seven baseline and seven follow-up days per patient), 231 (91.7%) were completed, with 21 days not being completed. Finally, 2,876 (88.8%) heart rhythm home measurements were performed out of 3,240 (two

daily measurements over 90 days for 18 patients).

FIGURE 3 Completeness of data.



PPG = photoplethysmography; SA = sleep apnoea.
a) Assessed by the number of days of activity tracking not monitored versus the total expected days.
b) Defined as heart rhythm measurements not obtained versus the total expected measurements.
c) Defined as the number of completed questionnaires versus the total expected questionnaires.
d) Measured by the number of SA home-evaluation nights not performed versus the total expected nights.

Outcomes

Supplementary Table 1 presents the outcome measures, including mean changes and confidence intervals. The mean changes are shown for the total population, as well as for two subgroups: those diagnosed with SA and subsequently treated with continuous positive airway pressure (CPAP), and those without SA who did not receive CPAP.

Discussion

Our study evaluated the feasibility of a fully decentralised platform for home-based SA screening in patients with AF. With a dropout rate of only 5% and an average 90% data completeness rate, we demonstrated that remote diagnostics and monitoring may achieve high engagement and reliable data collection. These results suggest that, with proper design and patient support, DCT challenges like dropout and data completeness can be effectively managed.

Completeness of home monitoring

Verhaert et al. demonstrated that remote monitoring for digital SA management produced a high patient satisfaction and a low dropout rate (10%) [7]. In our previous study using the NightOwl home monitoring device for patients with AF, the system proved to be user-friendly and effective for SA screening. Among 146 patients, 12 dropped out and eight had unsuccessful measurements, resulting in a 14% dropout rate [4]. Our 83.5% data completeness rate aligns with these findings. However, unlike Verhaert et al., who conducted only one night of

monitoring, our patients underwent at least two nights of monitoring. If limited to one night, our data would have been fully complete.

Telemonitoring for heart rhythm has been explored in several studies, many inspired by the COVID-19 pandemic [16, 17]. The TeleCheck-AF study instructed AF patients to measure heart rhythm three times daily for seven days using the FibriCheck app, achieving a mean adherence rate of 94% [16]. However, unlike TeleCheck-AF's seven-day monitoring, our study required 90 days of monitoring. Despite the challenges of long-term mobile health monitoring, which is often associated with declining adherence [18], we achieved an 89% adherence rate, underscoring the feasibility of our platform for extended monitoring in AF patients.

eHealth literacy

Compared to previously published data, our participants appeared to have a slightly higher digital health literacy. Bendtsen et al. reported lower eHLQ scores in a population of 90 in-hospital patients with osteoporosis. We conducted an exploratory comparison using available summary statistics and found a statistically significant difference only in eHLQ3 ("ability to actively engage with digital services"), with no significant differences being observed in the remaining domains [19]. This may be attributed to our recruitment strategy, which involved sign-up through a webpage. A similar study with in-hospital patients and a lower median age of 57 years also reported lower eHLQ scores [20]. Although health literacy generally declines with age, our findings suggest that the patients with AF in our study were relatively adept at interacting with digital health services. However, this group may not fully represent everyday AF patients, as recruitment via a webpage likely selected towards individuals with a higher digital literacy. To address this, future studies should assess eHLQ at baseline and tailor onboarding support accordingly. Multimodal recruitment strategies (e.g., in-clinic invitations, phone support) may help include participants with lower digital skills and mitigate bias, thereby ensuring more a equitable access.

Benefits and challenges of decentralized clinical trials

Unlike traditional clinical research, which often requires in-person visits and creates logistical barriers, DCTs offer a flexible, patient-focused approach. DCTs enable participation from home or work, removing travel barriers and facilitating continuous data collection via digital tools.

By allowing remote participation, DCTs broaden access to diverse patient populations and enhance generalisability. They also provide more accurate insights into patient health by capturing data in everyday settings. Despite concerns about dropout rates and incomplete data, our study demonstrated feasibility with a low dropout rate (5%) and high data completeness (90%), ensuring reliable data collection and strong engagement. However, this was based on a small sample and intensive patient support.

These findings align with recent ESC guidelines emphasising eHealth and digital technologies in AF management, highlighting DCTs as an effective solution for integrating remote monitoring into clinical practice. This approach reduces logistical burdens for patients and healthcare systems while enhancing participation and data quality.

Limitations

This study had several limitations. First, as a feasibility study for a larger national clinical trial, it utilised a convenience sample without a formal power calculation. The small sample size may limit the robustness and generalisability of the findings to the broader AF population. Second, recruitment through a website may have introduced selection bias, favouring individuals who were comfortable with digital health technologies. Third, key feasibility metrics, such as recruitment and screening success rates, were not evaluated.

Conclusions

This study demonstrated that a fully decentralised digital platform integrating home-based SA screening, questionnaires, heart rhythm monitoring and activity tracking is feasible and effective for patients with AF who are comfortable using digital tools. High adherence and low dropout support the use of digital health technologies in AF clinical trials.

Correspondence *Mads Hashiba.* E-mail: Mads.Hashiba.Jensen.01@regionh.dk

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Conflicts of interest NN and PJ report financial support from or interest in AstraZeneca and Bayer. SR reports financial support from or interest in Biotronik and Boston Scientific. ML reports financial support from or interest in Helsefonden, Danish Heart Foundation, Bristol Myers Squibb, Bayer and AstraZeneca. RAVF reports financial support from or interest in Novo Nordisk, AGB pharma and Jazz pharma. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. These are available together with the article at ugeskriftet.dk/dmj

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Supplementary material: https://content.ugeskriftet.dk/sites/default/files/2025-08/Supplementary_A12240892.doc.pdf

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